EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (ENGLAND AND WALES AND SCOTLAND) (AMENDMENT) (NO.2) REGULATIONS 2023

2023 No. 1345

1. Introduction

1.1 This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by the Command of His Majesty.

2. Purpose of the instrument

2.1 This instrument amends the Misuse of Drugs Regulations 2001 (S.I. 2001/3998) ("the 2001 Regulations") to enable the prescribing of five specified controlled drugs by paramedic independent prescribers and six specified controlled drugs by therapeutic radiographer independent prescribers. These drugs are listed in paragraph 7.10 below. As set out in paragraph 7.1 below, independent prescribing, subject to appropriate safeguards, will make prescribing in these circumstances more efficient.

2.2 The instrument also enables the supply of three codeine products, which are all Schedule 5 controlled drugs, by specified registered chiropodists and podiatrists. These are outlined in paragraph 7.11. This supply is already enabled by a "Written Authority" issued by the Secretary of State, as set out in paragraph 7.13. The amendment will provide greater clarity by placing the power on the face of the legislation.

2.3 The instrument makes technical amendments in relation to podiatrist independent prescribers and physiotherapist independent prescribers. The amendments are described in paragraph 7.16 and are intended to clarify the legislation.

2.4 The instrument also makes technical amendments to specify that possession of ketamine by paramedics and other healthcare professionals that supply or administer controlled drugs under a Patient Group Direction ("PGD"), is lawful, as intended. This is explained further in paragraph 7.19.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law) is England and Wales and Scotland.

4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England and Wales and Scotland.

5. European Convention on Human Rights

5.1 As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 This instrument is made under sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971 ("the 1971 Act"). Section 31(3) of the 1971 Act provides that the Secretary of State may not make regulations under the 1971 Act except after consultation with the Advisory Council on the Misuse of Drugs ("ACMD"). The ACMD has been consulted and approved the amendments listed in paragraph 2.1 to 2.4. The reports containing their advice are available on GOV.UK at the following links:

6.2 Independent prescribing of controlled drugs by therapeutic radiographers - GOV.UK (www.gov.uk) published on 5 September 2016, ACMD-Further-advice-therapeutic-radiographers.pdf (publishing.service.gov.uk) published on 19th January 2017 and ACMD advice on administration rights for therapeutic radiographer independent prescribers - GOV.UK (www.gov.uk) published on 22nd April 2020.

6.3 ACMD advice on independent prescribing by paramedics - GOV.UK (www.gov.uk) published on 18th October 2019.

6.4 ACMD advice on the interim podiatrists supply proposal from NHS England (accessible version) - GOV.UK (www.gov.uk) published on 14th June 2022.

6.5 The 2001 Regulations enable legitimate access to controlled drugs in healthcare. Whilst the Home Office has legislative responsibility for the 2001 Regulations, the policy area is shared with the Department of Health and Social Care (DHSC) and this instrument has been drawn up in consultation with DHSC. DHSC has responsibility for the Human Medicines Regulations 2012 ("the 2012 Regulations"), which govern the use of medicines in healthcare.

7. Policy background

What is being done and why?

7.1 This instrument enables the prescribing of specified controlled drugs in Schedules 2 to 5 to the 2001 Regulations by paramedic independent prescribers and therapeutic radiographer independent prescribers. It is the Government's position that prescribing, by qualified independent prescribers within their competency (and subject to robust governance, monitoring and training arrangements being in place) should be treated with the same confidence as prescribing by doctors. Independent prescribing ensures that patients are treated at the first point of care where clinically appropriate, rather than being referring to another clinician, thus delivering faster treatment for patients and reducing pressure on NHS staffing. This instrument implements the necessary changes to controlled drugs legislation to achieve this policy intent, in accordance with the ACMD's advice, in respect of paramedic independent prescribers and therapeutic radiographer independent prescribers.

7.2 This instrument also allows the supply of three codeine products by registered podiatrists and registered chiropodists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicine provided to align with Schedule 17 of the 2012 Regulations. Supply of codeine products by registered chiropodists and podiatrists is already enabled by a Written Authority issued by the Secretary of State under section 30 of the 1971 Act and pursuant to regulation 8(4) of the 2001 Regulations. This instrument will not change existing practice, but it will update and clarify the regulations and ensure greater consistency of care.

7.3 The instrument makes further amendments in relation to podiatrist independent prescribers and physiotherapist independent prescribers and specifies that possession of ketamine by healthcare professionals acting under patient group directions is lawful, as intended. This will improve the clarity of the 2001 Regulations by ensuring previous recommendations from the ACMD are implemented within them in a manner that is internally consistent and aligns with the 2012 Regulations.

7.4 These amendments follow recommendations from the ACMD, which is a statutory, independent advisory body established by the 1971 Act. The ACMD makes recommendations to Government on appropriate control of dangerous or otherwise harmful drugs, which includes advice on access for their legitimate use in healthcare, as provided for in the 2001 Regulations.

Paramedic Independent Prescribing and Therapeutic Radiographer Independent Prescribing

7.5 All paramedics are regulated by the Health and Care Professions Council (HCPC) and must be registered with the HCPC to practice in the UK. Independent prescribing is undertaken by advanced paramedics. Advanced practice is defined by Health Education England (HEE), and typically requires education to master's degree level or equivalent. Paramedic independent prescribers must have successfully completed a training course leading to an independent prescribing qualification and have that qualification entered against their name in the HCPC register. Paramedic independent prescribers will be defined in the 2001 Regulations by this instrument as having the same meaning as in the 2012 Regulations.

7.6 Therapeutic radiographers treat and care for patients with cancer through radiotherapy. Therapeutic radiographers are regulated by the HCPC and must be registered with the HCPC to practice in the UK. Therapeutic radiographer independent prescribers must have successfully completed a training course leading to an independent prescribing qualification and have that qualification entered against their name in the HCPC register. The other distinct category of radiographers are diagnostic radiographers, to whom this instrument does not apply. Diagnostic radiographers take lead responsibility for the management and care of patients undergoing a spectrum of clinical imaging examinations, together with associated image interpretation. Diagnostic radiographers are regulated by the HCPC but are not currently able to train to prescribe independently. Therapeutic radiographer independent prescribers will be defined in the 2001 Regulations by this instrument as having the same meaning as in the 2012 Regulations.

7.7 NHS England consulted on proposals to enable prescribing by paramedic independent prescribers between 26 February and 27 May 2015, including the prescribing of specified controlled drugs. The proposals were then reviewed by the Commission on Human Medicines (CHM). Changes to the 2012 Regulations came into force on 1 April 2018.

7.8 NHS England consulted on proposals to enable prescribing by radiographers at the same time in 2015, including the prescribing of specified controlled drugs. The proposals were then reviewed by the CHM. Changes to the 2012 Regulations came into force on 1 April 2016.

7.9 As set out in paragraph 6.1, the Secretary of State is under a statutory obligation to consult the ACMD before making changes to the 2001 Regulations. After

consultation, the ACMD recommended that both proposals be implemented through amendments to the 2001 Regulations. The Home Office accepted this advice.

7.10 The instrument authorises paramedic independent prescribers to prescribe and administer the following controlled drugs in Schedules 2 to 5 to the 2001 Regulations: morphine sulphate by oral administration or by injection; diazepam by oral administration or by injection; midazolam by oromucosal administration or by injection; lorazepam by injection; and codeine phosphate by oral administration. The instrument authorises therapeutic radiographer independent prescribers to prescribe and administer the following controlled drugs in Schedules 2 to 5 to the 2001 Regulations: tramadol by oral administration; lorazepam by oral administration; diazepam by oral administration; morphine by oral administration or by injection; oxycodone by oral administration; and codeine by oral administration. The instrument also makes several additional consequential amendments required to give effect to the intention of these proposals.

Registered Chiropodist and Registered Podiatrist Supply

7.11 The ACMD considered a proposal from NHS England to enable supply of co-codamol, co-dydramol and codeine phosphate by podiatrists. In 2022, the ACMD recommended that the Home Office amend the 2001 Regulations to complement the existing legislative framework in the 2012 Regulations to enable podiatrists to supply co-codamol, co-dydramol and codeine phosphate with necessary safeguards in place.

7.12 The ACMD's advice in paragraph 6.1.3 refers to this proposal for registered chiropodists and podiatrists as an "interim mechanism" with a longer-term proposal to follow the outcome of a public consultation. The long-term proposal under consideration by NHS-England is to extend independent prescribing, including the prescribing of a wider range of controlled drugs, by chiropodists and podiatrists. The Government will consult the ACMD prior to making any further changes to the 2001 Regulations.

7.13 Previously, podiatrists supplied the medicines listed in paragraph 7.12 under a "Group Authority" issued by the Home Office's Drugs and Firearms Licensing Unit. Currently, registered chiropodists and registered podiatrists (who meet the definition in the relevant paragraphs of Schedule 17 of the 2012 Regulations) supply these medicines under a written authority issued by the Secretary of State under section 30 of the 1971 Act, pursuant to regulation 8(4) of the 2001 Regulations. This instrument will replace the written authority, enabling the same practice to occur under the 2001 Regulations. The written authority will be revoked after this instrument comes into force.

7.14 The Royal College of Podiatry and NHS England report that there are no concerns with the supply of these medicines by podiatrists in their professional practice. The Government has further consulted the ACMD and it agreed that guidance issued on the applicable safeguards, including a restriction to a three-day supply of these drugs by registered chiropodists or podiatrists, is sufficient rather than including it in the 2001 Regulations.

Technical amendments

7.15 The instrument amends the 2001 Regulations to ensure alignment with the 2012 Regulations in respect of podiatrist independent prescribers and physiotherapist

independent prescribers; and for the possession of ketamine by healthcare professionals acting under a PGD.

7.16 The instrument will clarify that patient possession for administration, pursuant to a prescription by a podiatrist independent prescriber or physiotherapist independent prescriber is lawful. It will also amend the definition of "prescription" in the 2001 Regulations to include those issued by a podiatrist independent prescriber or a physiotherapist independent prescriber.

7.17 Appropriately qualified physiotherapists and podiatrists, who also have the relevant annotations in the HCPC register, are able to train to independently prescribe any licensed medicine provided it falls within their individual area of competence and respective scope of practice. A physiotherapist independent prescriber may prescribe any licensed medication within national and local guidelines for any condition within their area of expertise and competence in human movement, performance and function. A podiatrist independent prescriber can prescribe only those medicines which are relevant to the treatment of disorders affecting the foot, ankle and associated structures, in line with current practice and consistent with published professional guidance.

7.18 The Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2015 (S.I 891/2015) provided physiotherapist and podiatrist independent prescribers with limited independent prescribing rights. This was to improve safety and health outcomes for patients through improved access to medicines and more timely treatment. The current instrument ensures clarity by specifying the consequential effect on possession pursuant to a prescription, and the definition of "prescriptions", in a manner consistent with other independent prescribers.

7.19 The instrument will specify that possession of ketamine by healthcare professionals, including paramedics, that supply or administer controlled drugs under a PGD, is lawful, as intended. A PGD is a set of instructions which directs the healthcare professional in their assessment of a patient and indicates whether the patient should or should not have the medicine concerned. It is defined in the 2001 Regulations as having the same meaning as in the 2012 Regulations. PGDs allow particular healthcare professionals to be trained to assess a patient within stated parameters. A separate direction is needed for each medicine to be supplied or administered. Paramedics, nurses, pharmacists and other professions are able to use PGDs.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018 / implement any future relationship agreement with the European Union within the meaning provided by section 37 of the European Union (Future Relationship) Act 2020.

9. Consolidation

9.1 This instrument amends another instrument, the Misuse of Drugs Regulations 2001, which the Government intends to consolidate in the future.

10. Consultation outcome

10.1 NHS England conducted two public consultations in 2015, one on proposals to introduce independent prescribing by paramedics and the other for independent prescribing by radiographers. The vast majority of respondents gave approval for the changes being implemented. Summaries of the responses from each consultation were published by NHS England and were deemed sufficient to enable amendments to be made to the 2012 Regulations without the Government publishing a consultation response. No public consultation was conducted regarding the supply of codeine products by podiatrists as the issue predates the 2012 Regulations. However, prior to the introduction of the current written authority, the Royal College of Podiatry was consulted and agreed that supply of the specified codeine products by registered podiatrists should be allowed.

10.2 The ACMD has been consulted as statutorily required and the Government accepted its recommendations, which are outlined in paragraphs 7.1-7.19. The Home Office has also consulted the DHSC and NHS England who supported the changes being implemented.

11. Guidance

11.1 The law changes and their consequences will be communicated to key stakeholders, including healthcare professionals, and the wider public by the Home Office and DHSC. The Home Office will issue a circular explaining the changes further and DHSC will communicate them to the healthcare sector.

11.2 Guidance issued by NHS England and the professional bodies will be updated to reflect the law change. This will include guidance from the Royal College of Podiatry on safeguards that apply to the supply of codeine products.

12. Impact

12.1 The impact on the public sector, specifically the NHS, is moderate and beneficial. Paramedic independent prescribers and therapeutic radiographer independent prescribers will be able to prescribe a range of controlled drugs where clinically appropriate, without the need to refer to other clinicians. This will reduce pressure on NHS staffing and deliver faster treatment for patients. There will be a small cost to the NHS associated with the time taken for additional training, although this is not considered significant as NHS staff are already highly trained. There are no anticipated social costs.

12.2 The impact on business is positive but small, reflecting a relatively small market share for the relevant healthcare providers. There is no significant impact on charities or voluntary bodies from this instrument.

12.3 A full impact assessment will be published alongside the explanatory memorandum on legislation.gov.uk on the date the instrument is laid.

13. Regulating small business

13.1 The instrument applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses. The basis for the final decision on what action to take is that no impact on small business is identified from the impact assessment besides the potential savings to be

achieved from the proposals as a result of prescribing duties moving over to paramedic and therapeutic radiographer independent prescribers.

14. Monitoring & review

14.1 The Government will monitor the changes through the oversight of Controlled Drug Accountable Officers and the healthcare regulatory bodies in England, Wales and Scotland.

14.2 A statutory review clause is not included in the instrument.

15. Contact

15.1 Lauren Teer at the Home Office, Telephone: 07587299202 or email: lauren.teer@homeoffice.gov.uk can be contacted with any queries regarding the instrument.

15.2 Marcus Starling, Deputy Director for the Drug Misuse Unit at the Home Office can confirm that this explanatory memorandum meets the required standard.

15.3 The Minister for Crime, Policing and Fire, the Rt. Hon. Chris Philp MP, can confirm that this explanatory memorandum meets the required standard.